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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,573	03/22/2001	Hector F. DeLuca	1256-00721	9707

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/815,573	Applicant(s) DELUCA ET AL.	
	Examiner Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 0200* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 9, 2002 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed August 9, 2002 in Paper No. 10, and amendment and response to the Final Office Action (mailed February 12, 2002), filed August 9, 2002 in Paper No. 11 wherein claims 1-7 have been amended. Currently, claims 1-7 are pending in this application.

Applicant's amendment changing the limitation to "feeding as part of a daily diet" herein in claims 1-7 filed on August 9, 2002 in Paper No. 11 with respect to the rejections made under 35 U.S.C. 102(b) as being anticipated by DeLuca et al. (4,338,312), and made under 35 U.S.C. 102(b) as being anticipated by DeLuca et al. (4,110,446), for reasons of record stated in the Final rejection dated February 12, 2002 have been considered and are found persuasive to remove these particular rejections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (4,338,312 and 4,110,446, of record in the previous Office Actions February 12, 2002 and July 17, 2001).

DeLuca et al. (4,338,312) discloses that an oral administration to a dairy cow of a composition comprising a 1α-hydroxylated vitamin D such as 1α-hydroxy vitamin D_3 and 1α,25-dihydroxyvitamin D_3, within instant claim, with low phosphorus is useful in a method of treatment and prophylaxis for milk fever in dairy cattle. See '312 abstract, col.2 lines 54-65, col.3 Example, and claims 1, 3, and 10; '446 abstract, col.2 lines 37-49, col.5 lines 10-19, and claims 1, 3, and 5. DeLuca et al. also discloses the effective amounts of 1α-hydroxy vitamin D_3 i.e., 0.3-0.5 mg, and 1α,25-dihydroxyvitamin D_3 i.e., 2-4 mg, dissolved in corn oil to be administered. See col.2 lines 36-65. DeLuca et al. further discloses that administering 1α-hydroxylated vitamin D such as 1α-hydroxy vitamin D_3 with the diet containing low phosphorus was maintained throughout the parturition portion in the experiment. See col.3 lines 15-19.

DeLuca et al. (4,110,446) discloses that an oral administration to a dairy cow of a composition comprising a 1α-hydroxylated vitamin D such as 1α,25-dihydroxyvitamin

D_3, within instant claim, is useful in a method of treatment and prophylaxis for milk fever in dairy cattle. See abstract, col.2 lines 37-49, col.5 lines 10-19, and claims 1 and 6. DeLuca et al. also discloses that the range of the effective amounts of 1α,25-dihydroxyvitamin D_3 is 200-400 μg, dissolved in corn oil to be administered. See col.2 lines 36-65.

DeLuca et al. do not expressly disclose "feeding as part of a daily diet" an effective amount of a 1α-hydroxylated vitamin D herein and 0.1 to 100 μg/kg of 1α-hydroxylated vitamin D to be administered as a top dressing on the feed.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to motivated to feed as part of a daily diet an effective amount of a 1α-hydroxylated vitamin D herein and to optimize the effective amount of 1α-hydroxylated vitamin D to be administered to 0.1 to 100 μg/kg as a top dressing on the feed.

One having ordinary skill in the art at the time the invention was made would have been motivated to feed as part of a daily diet an effective amount of a 1α-hydroxylated vitamin D herein because an **oral** administration to a dairy cow of an effective amount of a 1α-hydroxylated vitamin D herein is known in the prior art. Moreover, an effective amount of a 1α-hydroxylated vitamin D herein is known to be administered with a cow diet containing low phosphorus throughout the parturition portion (milk fever). Further, feeding a known oral composition which is also known to administered with a cow diet, as part of daily diet to a dairy cow is considered well within

conventional skills in animal (food and nutritional) science or industry, involving merely routine skill in the art.

Additionally, one having ordinary skill in the art at the time the invention was made would have been motivated to optimize the effective amount of 1α-hydroxylated vitamin D to be administered to 0.1 to 100 μg/kg as a top dressing on the feed because the optimization of the known effective amounts of active agents herein to be administered in the form of top dressing on the feed is also considered well within the conventional skill of artisan.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Applicant's remarks filed August 9, 2002 in Paper No. 11 with respect to the rejections made under 35 U.S.C. 102(b) as being anticipated by DeLuca et al. (4,338,312), and made under 35 U.S.C. 102(b) as being anticipated by DeLuca et al. (4,110,446), and made under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (4,338,312 and 4,110,446), for reasons of record stated in the Final rejection dated February 12, 2002 have been fully considered. These remarks are believed to be adequately addressed by the obviousness rejection presented above and in the Final rejection (February 12, 2002).

Additionally, Applicants' arguments again regarding "in the dry period" in DeLuca '312 patent are not found convincing. As discussed in the Final rejection, DeLuca clearly discloses the method for prophylactically treating dairy cow for parturient paresis

comprising administering the instant compounds (see claims 1 and 3). Parturient paresis (milk fever) is known to be a metabolic disease of dairy cows including lactating dairy cows resulting from parturition and the initial formation of milk according to DeLuca (col.1 lines 8-15). Thus, the scope of DeLuca's method nowhere is limited to dairy cows "in the dry period". The Example (at col.3) in which the third lactation or better Holstein cows were fed in the dry period is merely a particular example of the method therein.

Applicants' arguments regarding "lactation no." in Tables 2 and 3 in DeLuca ' 446 patent are not found persuasive since DeLuca clearly discloses that the results in these tables are from the testing on the administration 1α,25-dihydroxyvitamin D_3 to cows during and post-calving period. Therefore, one of ordinary skill in the art would clearly recognize that "lactation no." would be the number of the offspring born by cow (as admitted by Applicants in the response page 6) that is in a lactating period.

Further, as discussed in the Final rejection, Applicant's results on testing the instant vitamin D compounds in the specification at pages 13-17 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention but are not deemed persuasive. The results of Tables 2-4 at pages 15-17 showing the effects of the instant vitamin D compounds are clearly expected for the instant claimed method based on the cited prior art. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Results herein provide no clear and convincing evidence of nonobviousness or unexpected results over the cited

prior art. Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
September 24, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER

9/30/02